

JC20 Rec'd PCT/PTO 16 MAY 2005

IN THE EUROPEAN PATENT OFFICE
AS INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International Application No. : PCT/US03/36488
International Filing Date : 17 November 2003 (17.11.2003)
Earliest Priority Date : 15 November 2002 (15.11.2002)
Applicant(s) : C.R. BARD, INC. ET AL.
Title : ELECTROPHYSIOLOGY CATHETER WITH
ABLATION ELECTRODE

Authorized Officer: Mayer-Martenson, E.

European Patent Office
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk – Pays Bas

RESPONSE TO WRITTEN OPINION
AND AMENDMENTS UNDER ARTICLE 34

In response to the Written Opinion mailed 28 May 2004 (28.05.2004), Applicant respectfully requests reconsideration of the above-identified application by the International Preliminary Examining Authority in view of the following remarks and amendments to the claims under PCT Article 34. Please substitute the enclosed sheets labeled as pages 14-18, and consider the pages filed herewith to establish the International Preliminary Examination Report.

Claims 1, 9, and 15 have been amended.

REMARKS

The Written Opinion indicated that, of the examined claims (claims 1-15), each of claims 1, 10-12, and 15 was not novel in view U.S. Patent No. 6,287,306 (reference D1), and that each of claims 2, 6, 8, 9, 13, and 14 did not meet the inventive step requirement in view of reference D1 together with one of a handful of additional references.

Applicant has amended independent claim 1 to clearly distinguish it over the cited references.

Each of claims 2-15, being dependent on claim 1, distinguishes over the cited references for at least the same reasons.

As amended, claim 1 is directed to an apparatus for ablating tissue that comprises a shaft and a tissue-ablating electrode. The claimed electrode comprises a first end portion and a middle portion supported by respective lengthwise sections of the shaft, wherein the total energy-emitting surface area of the electrode per unit length of the shaft is greater for the middle portion of the electrode than for the first end portion of the electrode.

Reference D1 discusses that the so-called "edge effects" of an electrode can be ameliorated by altering the resistance profile along the electrode's length. In particular, the patent illustrates, for a cylindrically-shaped electrode, the use of a higher-resistance material at the ends than is used in the middle can lower current densities in the ends relative to those in the middle, thus reducing the edge effects. The reference illustrates several embodiments of electrodes designed to achieve that objective. In all of the disclosed embodiments, however, the total energy-emitting surface area of the electrode per unit length of the shaft is the same in each portion of the electrode.

Reference D1 does not teach or suggest addressing the issue of edge effects by making those portions of the electrode that are generally subject to edge effects responsible for ablating more tissue than the other electrode portions. This novel technique is achieved by the claimed invention, wherein "the total energy-emitting surface area of the electrode per unit length of the shaft is greater for the middle portion of the electrode than for the first end portion of the electrode."

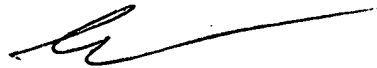
Based upon the above, issuance of a favorable report with respect to the amended claims is respectfully requested.

If for any reason this response does not place the application in condition for issuing a favorable International Preliminary Examination Report as to all claims, Applicant requests issuance of a further Written Opinion and an opportunity to respond thereto prior to issuance of the International Preliminary Examination Report. Should there be insufficient time available for issuance of a further Written Opinion, Applicant requests the IPEA to initiate a telephone interview at Applicants' expense,

JC20 Rec'd PCT/PTO 16 MAY 2005

and an opportunity to file a supplemental response to the previous Written Opinion by return fax, pursuant to PCT Article 34(2).

Respectfully submitted,



Robert M. Abrahamsen, Reg No.: 40,886
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
United States of America
Telephone: (617) 720-3500
Facsimile: (617) 720-2441

Docket No.: B1075.70036
Date: 26 July 2004

IN THE EUROPEAN PATENT OFFICE
AS INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

IC20 Rec'd PCT/PTO 1 6 MAY 2005

International Application No. : PCT/US03/36488
International Filing Date : 17 November 2003 (17.11.2003)
Earliest Priority Date : 15 November 2002 (15.11.2002)
Applicant(s) : C.R. BARD, INC. ET AL.
Title : ELECTROPHYSIOLOGY CATHETER WITH
ABLATION ELECTRODE

Authorized Officer: Mayer-Martenson, E.

European Patent Office
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk – Pays Bas

**RESPONSE TO WRITTEN OPINION
AMENDMENT UNDER PCT ARTICLE 34(2)(b)**

Transmitted herewith is the Response to the Written Opinion mailed 28 May 2004 (28.05.04). The following documents are included: the Amendments Under Article 34 (3 pages) and replacement pages 14-18 (5 pages).

Respectfully submitted,



Robert M. Abrahamsen, Reg No.: 40,886
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
United States of America
Telephone: (617) 720-3500
Facsimile: (617) 720-2441

Docket No.: B1075.70036
Date: 26 July 2004

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

10/534960
PCT

To:

Abrahamsen, Robert M.
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
ETATS-UNIS D'AMERIQUE

WRITTEN OPINION
(PCT Rule 66)

Date of mailing

(day/month/year) 23.11.2004

Applicant's or agent's file reference

B107570036

REPLY DUE

within 1 month(s)

from the above date of mailing

International application No.

PCT/US 03/36488

International filing date (day/month/year)

17.11.2003

Priority date (day/month/year)

15.11.2002

International Patent Classification (IPC) or both national classification and IPC

A61B18/14

DOCKETED

Applicant

C.R. BARD, INC. ET AL.

NOV 30 2004

Initials

Confirmation

Docketing

1. This written opinion is the **second** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 15.03.2005

Name and mailing address of the international preliminary examining authority:



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Mayer-Martenson, E

Formalities officer (incl. extension of time limits)

Rasmussen, S

Telephone No. +31 70 340-4595



JC20 Rec'd PCT/PTO 16 MAY 2005

WRITTEN OPINION

International application No. PCT/US 03/36488

I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-4, 6-13	as originally filed
5	received on 15.03.2004 with letter of 15.03.2004

Claims, Numbers

1-35	received on 26.07.2004 with letter of 26.07.2004
------	--

Drawings, Sheets

1/4, 3/4, 4/4	as originally filed
2/4	received on 15.03.2004 with letter of 15.03.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☒ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 16-35

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 16-35 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1,10-12,15
Inventive step (IS)	Claims	2,6,8,9,13,14
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

Re Item I

Basis of the report

The amendments filed with the letter dated 26.07.2004 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:

claims 1 and 15: "the total energy emitting surface area of the electrode per unit length of the shaft is greater for the middle portion of the electrode than for the first end portion of the electrode".

This feature is not explicitly disclosed in the originally filed description and claims. It is also not inherently disclosed in the description in the sense that the skilled person would immediately recognize it (PCT Guidelines ISPE/1/20.12) The application does also not contain enough examples for electrode configurations fulfilling the condition described in the amendment which would justify this broad formulation. In fact only a coiled conductor is clearly disclosed with either different cross sections or different spacings in different electrode sections.

Therefore an amended claim should be limited to subject matter actually disclosed. When filing amendments applicant should also indicate the basis in the description or the claims as originally filed on which the amendments are based on.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Since the amendments of claim 1 go beyond the content of the application as filed (Rule 70(2) (c) PCT) they are considered not to have been made. Therefore the subject matter of claim 1 as originally filed together with the dependent claims 2-15 represents the basis for this opinion. Hence applicant is referred to the previous opinion issued by the IPEA for the reasoning about lack of clarity, novelty and inventive step.

10/534960

** Transmit Conf. Report JC20 Rec'd PCT/PTO 1 6 MAY 2005

P.1

Dec 17 2004 16:04

Fax/Phone Number	Mode	Start	Time	Page	Result	Note
01131703403016#3927	NORMAL	17,16:04	1'43"	5	OK	CFS

Wolf, Greenfield & Sacks, P.C.

Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210
(617) 646-8000
Fax (617) 646-8646

FAX COVERSHEETDecember 17, 2004

Number of Pages (including coversheet): 5
 For the Attention of: Mayer-Martenson, E.
 Fax Number: 011 31-70-340-3016

Re: International Application No.: PCT/US03/36488
 International Filing Date: 17 November 2003 (17.11.2003)
 Earliest Priority Date: 15 November 2002 (15.11.2002)
 Applicant(s): C.R. BARD, INC. ET AL.
 Title: ELECTROPHYSIOLOGY
CATHETER WITH ABLATION
ELECTRODE

Our Reference No.: B1075.70036

Certification of Facsimile Transmission

The undersigned hereby certifies that a Response to Second Written Opinion is being facsimile transmitted to European Patent Office, P.B. 5818 Patentlaan 2, NL-2280 HV Rijswijk - Pays Bas, on 17 December, 2004.

Colleen F. Sullivan

Name



Signature

This transmission contains confidential information intended for use only by the above-named recipient. Reading, discussion, distribution, or copying of this message is strictly prohibited by anyone other than the named recipient, or his or her employees or agents. If you have received this fax in error, please immediately notify us by telephone at the above address via the U.S. Postal Service.

Wolf, Greenfield & Sacks, P.C.

Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210
(617) 646-8000
Fax (617) 646-8646

FAX COVERSHEET

December 17, 2004

Number of Pages (including coversheet): 5
For the Attention of: Mayer-Martenson, E.
Fax Number: 011 31-70-340-3016

Re: International Application No.: PCT/US03/36488
International Filing Date: 17 November 2003 (17.11.2003)
Earliest Priority Date: 15 November 2002 (15.11.2002)
Applicant(s): C.R. BARD, INC. ET AL.
Title: ELECTROPHYSIOLOGY
CATHETER WITH ABLATION
ELECTRODE
Our Reference No.: B1075.70036

Certification of Facsimile Transmission

The undersigned hereby certifies that a Response to Second Written Opinion is being facsimile transmitted to European Patent Office, P.B. 5818 Patentlaan 2, NL-2280 HV Rijswijk – Pays Bas, on 17 December, 2004.

Colleen F. Sullivan

Name



Signature

This transmission contains confidential information intended for use only by the above-named recipient. Reading, discussion, distribution, or copying of this message is strictly prohibited by anyone other than the named recipient, or his or her employees or agents. If you have received this fax in error, please immediately notify us by telephone (collect), and return the original message to us at the above address via the U.S. Postal Service.

If you did not receive all of the pages of this transmission or if any of the pages are illegible, please call immediately at (617) 646-8000.

IN THE EUROPEAN PATENT OFFICE
AS INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International Application No.: PCT/US03/36488
International Filing Date: 17 November 2003 (17.11.2003)
Earliest Priority Date: 15 November 2002 (15.11.2002)
Applicant(s): C.R. BARD, INC. ET AL.
Title: ELECTROPHYSIOLOGY CATHETER WITH
ABLATION ELECTRODE

Authorized Officer: Mayer-Martenson, E.

European Patent Office
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk – Pays Bas

RESPONSE TO SECOND WRITTEN OPINION

Transmitted herewith is the Response to the Second Written Opinion mailed 23
November 2004 (23.11.2004).

Respectfully submitted,



Robert M. Abrahamsen
Reg. No. 40,886
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
United States of America
Telephone: (617) 646-8000
Facsimile: (617) 646-8646

DOCKET NO.: B1075.70036
DATE: 17 December, 2004

THE EUROPEAN PATENT OFFICE
AS INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International Application No. : PCT/US03/36488
International Filing Date : 17 November 2003 (17.11.2003)
Earliest Priority Date : 15 November 2002 (15.11.2002)
Applicant(s) : C.R. BARD, INC. ET AL.
Title : ELECTROPHYSIOLOGY CATHETER WITH
ABLATION ELECTRODE

Authorized Officer: Mayer-Martenson, E.

European Patent Office
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk – Pays Bas

RESPONSE TO SECOND WRITTEN OPINION

In response to the Second Written Opinion mailed 23 November 2004 (23.11.2004), Applicant respectfully requests reconsideration of the above-identified application by the International Preliminary Examining Authority in view of the following remarks.

REMARKS

The Examined Claims

In Section V, Part 1 of the Second Written Opinion, it appears that the Examiner has identified the examined claims for which the stated conditions (i.e., Novelty, Inventive Step, and Industrial Applicability) do not exist, rather than identifying the examined claims that meet those conditions, as is usually the case. Thus, Applicant wishes to confirm that, for the examined claims, this Section was intended to communicate: (A) that claims 2-9, 13, and 14 are considered novel, (B) that claims 3-5, and 7 are considered to involve inventive step, and (C) that claims 1-15 are considered to have industrial applicability.

The Amended Claims

The Second Written Opinion asserted that the limitation of claims 1 and 15 requiring that "the total energy-emitting surface area of the electrode per unit length of the shaft is greater for the middle portion of the electrode than for the first end

portion of the electrode was not adequately disclosed in the originally-filed application and claims. The Second Written Opinion further asserted that the application did not contain enough examples for electrode configurations so as to “justify this broad formulation.” Applicant respectfully disagrees.

This feature is clearly disclosed in connection with the “second approach” introduced first at p. 4, line 21 – p. 5, line 9, as well as in originally-filed claims 9 and 18. As stated in the application, that second approach “involves somehow causing the portions of the electrode that are subjected to higher current densities due to edge effects to be responsible for ablating more tissue than the other portions of the electrode, thereby ensuring that the tissue along the entire path of an intended lesion pattern is subjected to a substantially uniform density of ablation energy.” P. 4, lines 22-26 (emphasis added). The specification further makes clear that “A number of techniques for achieving this objective also are disclosed, including, for example, separating spirals of a coiled electrode at locations near the ends of the electrode, while not separating, or separating to a lesser extent, the spirals in the inner portion of the coiled electrode.” P. 4, lines 26-29 (emphasis added).

The specification, moreover, goes on to state that this objective can be achieved not only with any of several coiled electrode configurations (including multiple conductor electrodes, coiled conductors having varying cross-sections, and recessed coiled conductors) but also with conventional ring electrodes having their surface areas suitably covered with a dielectric material. E.g., p. 11, lined 27-33.

Finally, and perhaps most tellingly, originally-filed claim 9 specifically recited that the claimed electrode “has a lower density of energy-emitting surface area in the vicinity of the first end portion than in the vicinity of the middle portion.” Although amended claims 1 and 15 use the words “energy-emitting surface area of the electrode per unit length of the shaft” rather than “density of energy-emitting surface area,” Applicant’s respectfully assert that an artisan in this field would understand these passages to have the same meaning.

Applicants thus request reconsideration and approval of the claim amendments submitted with Applicant’s response of 26 July 2004.

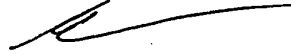
If for any reason this response does not place the application in condition for issuing a favorable International Preliminary Examination Report as to all claims, Applicant requests issuance of a further Written Opinion and an opportunity to

JC20 Rec'd PCT/PTO 16 MAY 2005

respond thereto prior to issuance of the International Preliminary Examination Report.

Should there be insufficient time available for issuance of a further Written Opinion, Applicant requests the IPEA to initiate a telephone interview at Applicant's expense, and an opportunity to file a supplemental response to the previous Written Opinion by return fax, pursuant to PCT Article 34(2).

Respectfully submitted,



Robert M. Abrahamsen
Reg No.: 40,886
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
United States of America
Telephone: (617) 646-8000
Facsimile: (617) 646-8646

Docket No.: B1075.70036

Date: 17 December 2004